

Study Group Working Notes #7: Scope of Regulations / Definition of “Stem Cells”

Study Group: NA

Background: Definitions can serve to define the scope of regulations and make them consistent and effective. Proposition 71 and existing California regulations apply to a broader scope of materials than the National Academies Guidelines.

The National Academies Guidelines address human embryonic stem cells. CIRM-funded research applies to a broader range of materials including but not limited to adult stem cells, fetal tissue and placenta derived cells. Proposition 71 includes definitions of “adult stem cells,” “pluripotent cells,” “stem cells,” (see below) in addition existing language in the CA Health and Safety Code applies to a broader range of materials (see below). A key question is: what is the most appropriate definition for the Draft CIRM Regulations?

Current P71 Definitions:

“Adult stem cell” means an undifferentiated cell found in a differentiated tissue in an adult organism that can renew itself and may, with certain limitations, differentiate to yield all the specialized cell types of the tissue from which it originated.

“Pluripotent cells” means cells that are capable of self renewal, and have broad potential to differentiate into multiple adult cell types. Pluripotent stem cells may be derived from somatic cell nuclear transfer or from surplus products of in vitro fertilization treatments when such products are donated under appropriate informed consent procedures. These excess cells from in vitro fertilization treatments would otherwise be intended to be discarded if not utilized for medical research.

“Stem cells” mean non-specialized cells that have the capacity to divide in culture and to differentiate into more mature cells with specialized functions.

Current CA Health and Safety Code:

California Health and Safety Code Section 125300(a) applies to the range of materials described in Proposition 71.

125300. *The policy of the State of California shall be as follows:*

(a) That research involving the derivation and use of human embryonic stem cells, human embryonic germ cells, and human adult stem cells from any source, including somatic cell nuclear [transfer] transplantation, shall be permitted and that full consideration of the ethical and medical implications of this research be given.

12.1.05 Standards Working Group Meeting

AGENDA ITEM # 6

Working Notes: Definitions

Options & Analysis:

The CIRM regulations could be limited initially to hES and then expanded over time. Ultimately they will need to cover the range of materials described in Proposition 71. Some Working Group members have suggested starting initially with hES and then expanding to scope over time to cover the range of materials. The value of this approach is that it would initially result in regulations substantially equivalent to the NA Guidelines.

Expanding the definition of stem cells would have the benefit of making the regulations comprehensive in scope. We have consulted the Grants Team at CIRM to consider what the scope of materials might be used in by institutions in the Training Grant Program. Since this will be the first set of grants funded by CIRM, it would be prudent that our regulations cover the scope of activity reasonably anticipated under this program.

Based on the intuitions research portfolios, the Grants Team indicated that they expect some trainees to be working with materials other than embryonic stem cells. This information suggests that there is a short term need to have regulations that cover more than embryonic stem cells.

Recommendation and/or Proposed Language:

In the interest of developing regulations that are sufficiently comprehensive for the range of funded activities, we recommend adopting a broad definition consistent with Proposition 71 and existing California regulations.

Stem cells refer to cells that are capable of self-renewal, and have potential to differentiate into multiple cell types.

This definition is sufficiently broad to cover the scope of activities reasonably anticipated in the training grants. This definition also appears to be consistent with Proposition 71 and the Existing California Health and Safety Code.